DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EndoGastric Solutions, Inc.
Mr. Michael A. Daniel
Vice President, Regulatory and Clinical Affairs
8210 154th Avenue, N.E.
Redmond, WA 98052

JUL 27 2015

Re: K062875
Trade/Device Name: EndoGastric StomaphyX Device and Accessories
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): February 21, 2007
Received (Date on orig SE ltr): February 22, 2007

Dear Mr. Daniel,

This letter corrects our substantially equivalent letter of March 9, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062875

Device Name: **EndoGastric StomaphyX Device and Accessories**

Indications For Use:

The EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the GI tract.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062875

Page 1 of 1

3. 510(k) SUMMARY

MAR 0 9 2007

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K062875

Applicant Information:

Date Prepared:	February 21, 2007
Date last revised:	March 9, 2007
Name:	EndoGastric Solutions, Inc.
Address:	8210 154th Avenue N.E. Redmond, WA 98052 Phone: 425 307 9200 Fax: 425 307 9201
Contact Person:	Michael A. Daniel
Phone Number:	Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number:	(925) 254-5187

Device Information:

Classification:	Class II
Trade Name:	EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system
Common Name:	Endoscopic Clip Applier, Implantable Fastener and Accessories
Classification Name:	Endoscope and Accessories 78 KOG / 21 CFR 876.1500

Predicate Devices:

The EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is substantially equivalent in intended use and method of operation to a combination of the following predicate devices:

K011016 – LSI Solutions Flexible Suture Placement Device & Accessories
K994290 – Bard Endoscope Suturing System / Bard EndoCinch (K003956)

Device Description:

The EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system consist of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. The unit is provided sterile and is a single use device. The polypropylene fasteners are proprietary and function only with the StomaphyX device. The device uses vacuum to invaginate tissue through a port into a chamber and fasten it using H shaped polypropylene fasteners. The fastener delivery subsystem is comprised of 3 elements: stylet, pusher, and internal lumens. They run the length of the device, the pusher being a hollow tube that rides over the length of the stylet, both riding in the lumen. The stylet is sharp at the distal tip to pierce tissue. The fastener is loaded by snapping it onto the stylet in the loading port of the handle. When pushed by the operator, the stylet carries the fastener down the lumen which runs from the proximal handle assembly to the distal tissue port where it will eventually be deployed into the tissue.

Intended Use:

The EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the GI tract.

Comparison to Predicate Device(s):

The design of the EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is similar to the predicates listed in that they are all devices designed to reach the desired suture location under endoscopic visualization, grasp tissue in some fashion and place sutures/clips in a desired location. All products are re-loadable for repeat fastener/suture/clip placement. The products all share common features such as a sterile, stainless steel needle (called a stylet in the StomaphyX device) housed in a suture loading unit. They all deliver fastener/suture/clips through soft tissue by manually actuating the needle with a handle mechanism. All devices are packaged sterile and are for single patient use. Further, the EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system and the predicate devices have the same or similar intended use, which is to place sutures/clips (fasteners) to approximate soft tissue under endoscopic visualization.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the EndoGastric StomaphyX Device has been shown to be substantially equivalent to currently marketed predicate devices.